

Application No. 10/790,338

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remains under examination in the application are presented below. The claims are presented in ascending order and each includes one status identifier.

1. (Withdrawn) A method of making a coating on a medical device for delivery of a therapeutic agent, the method comprising associating a composition with at least a portion of the device to form a first layer, wherein the composition comprises the therapeutic agent associated with a copolymer that has a molecular weight of at least about 2500, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit.
2. (Withdrawn) The method of claim 1, wherein the second monomer unit has a glass transition temperature that is at least about 50 degrees Centigrade higher than the glass transition temperature of the first monomer unit.
3. (Withdrawn) The method of claim 1, wherein the second monomer unit has a glass transition temperature that is at least about 70 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

Application No. 10/790,338

4. (Withdrawn) The method of claim 1 wherein the first monomer unit comprises an acrylate and the second monomer unit compromises a methacrylate.

5. (Withdrawn) The method of claim 1 wherein the first monomer unit and the second monomer unit selected from a member of the group consisting of acrylic acid, acrylonitrile, allyamine, acrylates, methacrylates, methylmethacrylate, alkyl acrylates, alkyl methacrylate, butadiene, carbomethylsilane, (carbonate) urethane, acrylates of polydimethyl siloxanes, methacrylates of polydimethyl siloxanes, ethylene, ethylene glycol, propylene glycol, (ether) urethane, urethane, vinyl chloride, vinyl alcohol, maleic anhydride, cellulose nitrate, carboxy methyl cellulose, dextran, dextran sulphate, propylene, esters, carbonates, ethers, butenes, maleic acid, fluoropolymer monomeric units, unsaturated polymer monomeric units, isoprene, melamine, sulphone, ureas, biological polymer monomeric units, protein, gelatin, collagen, elastin, butyl methacrylate, hydroxyethyl methacrylate, methacrylate acid, polyethylene glycol dimethacrylate, polypropylene glycol diglycidal ether, polyethylene glycol diglycidyl ether, isocyanatoethyl methacrylate, N-acryloxysuccinimide, glycidyl methacrylate, hexamethylene diisocyanate, acrolein, crotonaldehyde, glycerol monomethacrylate, heparin methacrylate, methacryloyl ethyl phosphorylcholine, polymethacrylate, polyacrylate, polyester, polyether, polyethylene glycol, butyl acrylate, polyethylene glycol monomethacrylate, isobutyl methacrylate, cyclohexyl methacrylate, ethyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, methyl acrylate, hexadecyl methacrylate, octadecyl methacrylate, styrene, methyl styrene, vinyl stearate, vinyl toluene, and tert-butyl acrylate.

Application No. 10/790,338

6. (Withdrawn) The method of claim 1 wherein the copolymer further comprises a third monomer unit, wherein the third monomer unit forms a homopolymer with a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of a homopolymer formed by the first monomer unit.
7. (Withdrawn) The method of claim 6 wherein the first monomer unit comprises an acrylate, the second monomer unit comprises a methacrylate, and the third monomer unit comprises a methacrylate.
8. (Withdrawn) The method of claim 1 wherein the copolymer is formed by covalently joining a homopolymer of the first monomer unit and a homopolymer of the second monomer unit.
9. (Withdrawn) The method of claim 8 wherein a first polymer comprises a first monomer unit and a second polymer comprises at least one member of the group consisting of the first monomer unit, the second monomer unit, and both the first monomer unit and the second monomer unit.
10. (Withdrawn) The method of claim 1 wherein the copolymer comprises at least two methacrylate monomer units.

Application No. 10/790,338

11. (Withdrawn) The method of claim 1 wherein the copolymer comprises a member of the group consisting of poly(hydroxyethyl methacrylate-co-butylacrylate-co-butylmethacrylate), poly(hydroxyethyl methacrylate-co-lauryl methacrylate), poly(polyethylene glycol monomethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(heparin methacrylate-co-hydroxyethylmethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(glycerol monomethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(amino methacrylate hydrochloride-co-butyl acrylate-co-butyl methacrylate), poly(isocyanatoethyl methacrylate-co-butyl acrylate-co-butyl methacrylate) and poly(methoxy(polyethylene glycol) monomethacrylate-co-lauryl methacrylate-co-butyl methacrylate-co-ethylene glycol dimethacrylate).

12. (Withdrawn) The method of claim 1 wherein the associating of the composition comprises applying the therapeutic agent and the copolymer to the device approximately simultaneously to form the composition in association with the device.

13. (Withdrawn) The method of claim 1 wherein the associating of the composition comprises spraying the therapeutic agent and the copolymer on the medical device, or dipping the medical device into a mixture of the therapeutic agent and the copolymer.

14. (Withdrawn) The method of claim 1 wherein the monomer units are polymerized to form the copolymer after the monomer units have been associated with the medical device.

Application No. 10/790,338

15. (Withdrawn) The method of claim 14 wherein the medical device is heated to polymerize the monomer units to form the copolymer.

16. (Withdrawn) The method of claim 14 wherein an initiator is associated with the monomer units and the initiator is activated to cause the polymerization of the monomer units to form the copolymer.

17. (Withdrawn) The method of claim 14 wherein the medical device is a stent and the therapeutic agent is paclitaxel.

18. (Withdrawn) The method of claim 17 further comprising implantating the device into a patient resulting in the release of the paclitaxel from the stent.

19. (Withdrawn) The method of claim 1 wherein the copolymer is prepared and is subsequently associated with the therapeutic agent.

20. (Withdrawn) The method of claim 1 wherein the copolymer is prepared from the monomer units from a melt of the monomers.

21. (Withdrawn) The method of claim 1 wherein the first monomer unit and the second monomer unit are chosen so that the first monomer unit reacts to form a plurality of blocks

Application No. 10/790,338

consisting essentially of repeats of the first monomer unit and the second monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the second monomer unit.

22. (Withdrawn) The method of claim 1 further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

23. (Withdrawn) The method of claim 22 wherein the first layer is at least partially disposed between the device and the second layer.

24. (Withdrawn) The method of claim 22 wherein the second layer is at least partially disposed between the device and the first layer.

25. (Withdrawn) The method of claim 22 wherein the second layer comprises a polymer that is covalently crosslinked to the polymer of the first layer.

26. (Withdrawn) The method of claim 22 wherein the copolymer comprises reactive functional groups that are involved in forming covalent crosslinks with the second layer, and wherein the reactive functional groups are chosen from the group consisting of hydroxyl, amine, carboxylic, aldehyde, ketone, thiol, allyl, acrylate, methacrylate, isocyanate, epoxide, azides, aziridines, acetals, ketals, alkynes, acyl halides, alkyl halides, hydroxy aldehydes and ketones, allenes, amides, bisamides, amino acids and esters, amino carbonyl compounds, mercaptans,

Application No. 10/790,338

amino mercaptans, anhydrides, azines, azo compounds, azoxy compounds, boranes, carbamates, carbodimides, carbonates, diazo compounds, isothionates, hydroxamic acid, hydroxy acids, hydroxy amines and amides, hydroxylamine, imines, lactams, nitriles, sulphonamides, sulphones, sulphonic acids, thiocyanates, and combinations thereof.

27. (Withdrawn) The method of claim 22 wherein the second layer comprises a heparin macromer that comprises a second reactive functional group that is involved in forming the crosslinks with the first layer.

28. (Withdrawn) The method of claim 22 wherein the polymer of the second layer comprises monomer units that comprise a heparin macromer.

29. (Withdrawn) The method of claim 22 wherein the polymer of the second layer comprises a second functional group that forms at least one of the covalent crosslinks in response to exposure to light.

30. (Withdrawn) The method of claim 22 wherein the second functional group comprises azide.

31. (Withdrawn) The method of claim 22 wherein the first layer comprises the therapeutic agent and the second layer does not comprise the therapeutic agent.

Application No. 10/790,338

32. (Withdrawn) The method of claim 31 wherein the second layer reduces the rate of release of the therapeutic agent from the first layer.
33. (Withdrawn) The method of claim 22 wherein the second layer is in contact with the medical device and comprises a polymer having at least one reactable monomer.
34. (Withdrawn) The method of claim 31 wherein the at least one reactable monomer is a member of the group consisting of acrylates and methylmethacrylates.
35. (Withdrawn) The method of claim 31 wherein the polymer in the second layer is a second copolymer that comprises monomer units of at least one member of the group consisting of vinyl chloride, vinyl acetate, and co-vinyl alcohol.
36. (Withdrawn) The method of claim 33 wherein the polymer in the second layer comprises a hydrophillic polymer.
37. (Withdrawn) The method of claim 36 wherein the polymer in the second layer comprises polyvinylpyrrolidone.
38. (Withdrawn) The method of claim 22 further comprising a third layer having a composition different from the first layer and the second layer.

Application No. 10/790,338

39. (Withdrawn) The method of claim 1 wherein the therapeutic agent is a member of the group consisting of, vasoactive agents, neuroactive agents, hormones, growth factors, cytokines, anaesthetics, steroids, anticoagulants, anti-inflammatories, immunomodulating agents, cytotoxic agents, antibiotics, antivirals, antibodies, anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, antibodies capable of blocking smooth muscle cell proliferation, hirudin, acetylsalicylic acid; anti-inflammatory agents, dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; anti-coagulants, D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, antiplatelet peptides, vascular cell growth promoters, growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, translational promoters, vascular cell growth inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, cholesterol-lowering agents, vasodilating agents, agents which interfere with endogenous vasoactive mechanisms, a radiopharmaceutical, an analgesic drug, an anesthetic agent, an anorectic agent, an anti-anemia agent, an anti-asthma agent, an anti-diabetic agent, an antihistamine, an anti-inflammatory drug, an antibiotic drug, an antimuscarinic drug, an anti-neoplastic drug, an antiviral drug, a cardiovascular drug, a central nervous system stimulator, a central nervous system depressant, an

Application No. 10/790,338

anti-depressant, an anti-epileptic, an anxyolytic agent, a hypnotic agent, a sedative, an anti-psychotic drug, a beta blocker, a hemostatic agent, a hormone, a vasodilator, a vasoconstrictor, and a vitamin.

40. (Withdrawn) The method of claim 1 wherein the therapeutic agent comprises paclitaxel.

41. (Withdrawn) The method of claim 1 wherein the device is selected from the group consisting of an implantable device, a device used topically on a patient, a device that contacts a living tissue, a catheter; a guide-wires, an embolizing coil; a vascular graft, a heart valve, an implantable cardiovascular defibrillator, a pacemaker, a surgical patch, a wound closure, a microsphere, a biosensors, an implantable sensor, an ex-vivo sensor, an ocular implant, a contact lens; and a tissue engineering scaffold.

42. (Withdrawn) The method of claim 1 wherein the device comprises a stent.

43. (Withdrawn) The method of claim 1 wherein the therapeutic agent comprises paclitaxel and the device comprises a stent.

44. (Withdrawn) The method of claim 1 wherein the glass transition temperature of the first monomer unit is below about 37 degrees Centigrade and the glass transition temperature of the second monomer unit is above about 37 degrees Centigrade.

Application No. 10/790,338

45. (Withdrawn) The method of claim 1 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about -70 to about 70 degrees Celsius.

46. (Withdrawn) The method of claim 1 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about 0 to about 60 degrees Celsius.

47. (Withdrawn) The method of claim 1 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about 15 to about 40 degrees Celsius.

48. (Withdrawn) The method of claim 47 wherein the combination comprises at least one monomer unit selected from the group consisting of butyl acrylate, butyl methacrylate, and hydroxyethylmethacrylate.

49. (Withdrawn) The method of claim 47 wherein the first monomer unit and the second monomer unit are selected from a member of the group consisting of acrylic acid, acrylonitrile, allyamine, acrylates, methacrylates, methylmethacrylate, alkyl acrylates, alkyl methacrylate, butadiene, carbomethylsilane, (carbonate) urethane, acrylates of polydimethyl siloxanes / methacrylates of polydimethyl siloxane ethylene, ethylene glycol, propylene glycol, (ether) urethane, urethane, vinyl chloride, vinyl alcohol, maleic anhydride, cellulose nitrate, carboxy

Application No. 10/790,338

methyl cellulose, dextran, dextran sulphate, propylene, esters, carbonates, ethers, butenes, maleic acid, fluoropolymer monomeric units, unsaturated polymer monomeric units, isoprene, melamine, sulphone, ureas, biological polymer monomeric units, protein, gelatin, collagen, elastin, butyl methacrylate, hydroxyethyl methacrylate, acrylic acid, methacrylate acid, polyethylene glycol dimethacrylate, polypropylene glycol diglycidal ether, polyethylene glycol diglycidyl ether, isocyanatoethyl methacrylate, N-acryloxysuccinimide, glycidyl methacrylate, hexamethylene diisocyanate, acrolein, crotonaldehyde, glycerol monomethacrylate, heparin methacrylate, methacryloyloxyethyl, methacryloylethyl phosphorylcholine polyacrylate, polyester, polyether, polyethylene glycol, butyl acrylate, polyethylene glycol monomethacrylate, isobutyl methacrylate, cyclohexyl methacrylate, ethyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, methyl acrylate, hexadecyl methacrylate, octadecyl methacrylate, styrene, methyl styrene, vinyl stearate, vinyl toluene, and tert-butyl acrylate.

50. (Withdrawn) The method of claim 47 wherein the copolymer further comprises a third monomer unit, wherein the third monomer unit forms a homopolymer with a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of a homopolymer formed by the first monomer unit.

51. (Withdrawn) The method of claim 50 wherein the first monomer unit comprises an acrylate, the second monomer unit comprises a methacrylate, and the third monomer unit comprises a methacrylate.

Application No. 10/790,338

52. (Withdrawn) The method of claim 47 wherein the copolymer comprises at least two methacrylate monomer units.

53. (Withdrawn) The method of claim 47 wherein the therapeutic agent and the copolymer are applied to the device approximately simultaneously.

54. (Original) A coating for a medical device for delivery of a therapeutic agent, the coating comprising a layer having a composition associated with at least a portion of the device, wherein the composition comprises the therapeutic agent associated with a copolymer that has a molecular weight of at least about 2500, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit.

55. (Original) The coating of claim 54 wherein at least a portion of the first monomer units are organized into a plurality of blocks consisting essentially of repeats of the first monomer unit, and at least a portion of the second monomer units are organized into a plurality of blocks consisting essentially of repeats of the second monomer unit.

56. (Original) The coating of claim 55 wherein the copolymer further comprises regions of random copolymer bonding.

Application No. 10/790,338

57. (Original) The coating of claim 54 wherein the copolymer comprises a third monomer unit and comprises at least three blocks, wherein each block consists essentially of repeats of one type of monomer unit.

58. (Original) The coating of claim 54 wherein the copolymer comprises acrylate blocks and methacrylate blocks.

59. (Original) The coating of claim 54 wherein the therapeutic agent associates with blocks within the copolymer.

60. (Original) The coating of claim 54, wherein the second monomer unit has a glass transition temperature that is at least about 50 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

61. (Original) The coating of claim 54, wherein the second monomer unit has a glass transition temperature that is at least about 70 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

62. (Original) The coating of claim 54 wherein the first monomer unit comprises an acrylate and the second monomer unit comprises a methacrylate.

Application No. 10/790,338

63. (Original) The coating of claim 54 wherein the first monomer unit and the second monomer unit selected from a member of the group consisting of acrylic acid, acrylonitrile, allyamine, acrylates, methacrylates, methylmethacrylate, alkyl acrylates, alkyl methacrylate, butadiene, carbomethylsilane, (carbonate) urethane, acrylates of polydimethyl siloxanes, methacrylates of polydimethyl siloxanes, ethylene, ethylene glycol, propylene glycol, (ether) urethane, urethane, vinyl chloride, vinyl alcohol, maleic anhydride, cellulose nitrate, carboxy methyl cellulose, dextran, dextran sulphate, propylene, esters, carbonates, ethers, butenes, maleic acid, fluoropolymer monomeric units, unsaturated polymer monomeric units, isoprene, melamine, sulphone, ureas, biological polymer monomeric units, protein, gelatin, collagen, elastin, butyl methacrylate, hydroxyethyl methacrylate, methacrylate acid, polyethylene glycol dimethacrylate, polypropylene glycol diglycidal ether, polyethylene glycol diglycidyl ether, isocyanatoethyl methacrylate, N-acryloxysuccinimide, glycidyl methacrylate, hexamethylene diisocyanate, acrolein, crotonaldehyde, glycerol monomethacrylate, heparin methacrylate, methacryloylethyl phosphorylcholine, polymethacrylate, polyacrylate, polyester, polyether, polyethylene glycol, butyl acrylate, polyethylene glycol monomethacrylate, isobutyl methacrylate, cyclohexyl methacrylate, ethyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, methyl acrylate, hexadecyl methacrylate, octadecyl methacrylate, styrene, methyl styrene, vinyl stearate, vinyl toluene, and tert-butyl acrylate.

64. (Original) The coating of claim 54 wherein the copolymer further comprises a third monomer unit, wherein the third monomer unit forms a homopolymer with a glass transition

Application No. 10/790,338

temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of a homopolymer formed by the first monomer unit.

65. (Original) The coating of claim 64 wherein the first monomer unit comprises an acrylate, the second monomer unit comprises a methacrylate, and the third monomer unit comprises a methacrylate.

66. (Original) The coating of claim 64 wherein the copolymer comprises a homopolymer of the first monomer unit covalently joined to a homopolymer of the second monomer unit.

67. (Original) The coating of claim 66 wherein a first polymer comprises a first monomer unit and a second polymer comprises at least one member of the group consisting of the first monomer unit, the second monomer unit, and both the first monomer unit and the second monomer unit.

68. (Original) The coating of claim 54 wherein the copolymer comprises at least two methacrylate monomer units.

69. (Original) The coating of claim 54 wherein the copolymer comprises a member of the group consisting of poly(hydroxyethyl methacrylate-co-butylacrylate-co-butylmethacrylate), poly(hydroxyethyl methacrylate-co-lauryl methacrylate), poly(polyethylene glycol monomethacrylate-co-butyl acrylate-co-butyl methacrylate),

Application No. 10/790,338

poly(heparin methacrylate-co-hydroxyethylmethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(glycerol monomethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(amino methacrylate hydrochloride-co-butyl acrylate-co-butyl methacrylate), poly(isocyanatoethyl methacrylate-co-butyl acrylate-co-butyl methacrylate) and poly(methoxy(polyethylene glycol) monomethacrylate-co-lauryl methacrylate-co-butyl methacrylate-co-ethylene glycol dimethacrylate).

70. (Original) The coating of claim 54 wherein the monomer units are polymerizable to form the copolymer after the monomer units have been associated with the medical device.

71. (Original) The coating of claim 54 wherein the medical device is a stent and the therapeutic agent is paclitaxel.

72. (Original) The coating of claim 54 wherein the copolymer is prepared and is subsequently associated with the therapeutic agent.

73. (Original) The coating of claim 54 wherein the copolymer is prepared from the monomer units from a melt of the monomers.

74. (Original) The coating of claim 54 wherein the first monomer unit and the second monomer unit are chosen so that the first monomer unit reacts to form a plurality of blocks

Application No. 10/790,338

consisting essentially of repeats of the first monomer unit and the second monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the second monomer unit.

75. (Original) The coating of claim 54 further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

76. (Original) The coating of claim 75 wherein the first layer is at least partially disposed between the device and the second layer.

77. (Original) The coating of claim 75 wherein the second layer is at least partially disposed between the device and the first layer.

78. (Original) The coating of claim 75 wherein the second layer comprises a polymer that is covalently crosslinked to the polymer of the first layer.

79. (Original) The coating of claim 75 wherein the copolymer comprises reactive functional groups that are involved in forming covalent crosslinks with the second layer, and wherein the reactive functional groups are chosen from the group consisting of hydroxyl, amine, carboxylic, aldehyde, ketone, thiol, allyl, acrylate, methacrylate, isocyanate, epoxide, azides, aziridines, acetals, ketals, alkynes, acyl halides, alky halides, hydroxy aldehydes and ketones, allenes, amides, bisamides, amino acids and esters, amino carbonyl compounds, mercaptans, amino

Application No. 10/790,338

mercaptans, anhydrides, azines, azo compounds, azoxy compounds, boranes, carbamates, carbodimides, carbonates, diazo compounds, isothionates, hydroxamic acid, hydroxy acids, hydroxy amines and amides, hydroxylamine, imines, lactams, nitriles, sulphonamides, sulphones, sulphonic acids, thiocyanates, and combinations thereof.

80. (Original) The coating of claim 75 wherein the second layer comprises a heparin macromer that comprises a second reactive functional group that is involved in forming the crosslinks with the first layer.

81. (Original) The coating of claim 75 wherein the polymer of the second layer comprises monomer units that comprise a heparin macromer.

82. (Original) The coating of claim 75 wherein the polymer of the second layer comprises a second functional group that forms at least one of the covalent crosslinks in response to exposure to light.

83. (Original) The coating of claim 75 wherein the second functional group comprises azide.

84. (Original) The coating of claim 75 wherein the first layer comprises the therapeutic agent and the second layer does not comprise the therapeutic agent.

Application No. 10/790,338

85. (Original) The coating of claim 75 wherein the second layer reduces the rate of release of the therapeutic agent from the first layer.
86. (Original) The coating of claim 75 wherein the second layer is in contact with the medical device and comprises a polymer having at least one reactable monomer.
87. (Original) The coating of claim 86 wherein the at least one reactable monomer is a member of the group consisting of acrylates and methacrylates.
88. (Original) The coating of claim 87 wherein the polymer in the second layer is a second copolymer that comprises monomer units of at least one member of the group consisting of vinyl chloride, vinyl acetate, and co-vinyl alcohol.
89. (Original) The coating of claim 87 wherein the polymer in the second layer comprises a hydrophilic polymer.
90. (Original) The coating of claim 89 wherein the polymer in the second layer comprises polyvinylpyrrolidone.
91. (Original) The coating of claim 75 further comprising a third layer having a composition different from the first layer and the second layer.

Application No. 10/790,338

92. (Original) The coating of claim 54 wherein the therapeutic agent is a member of the group consisting of, vasoactive agents, neuroactive agents, hormones, growth factors, cytokines, anaesthetics, steroids, anticoagulants, anti-inflammatories, immunomodulating agents, cytotoxic agents, antibiotics, antivirals, antibodies, anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, antibodies capable of blocking smooth muscle cell proliferation, hirudin, acetylsalicylic acid; anti-inflammatory agents, dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; anti-coagulants, D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, antiplatelet peptides, vascular cell growth promoters, growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, translational promoters, vascular cell growth inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, cholesterol-lowering agents, vasodilating agents, agents which interfere with endogenous vasoactive mechanisms, a radiopharmaceutical, an analgesic drug, an anesthetic agent, an anorectic agent, an anti-anemia agent, an anti-asthma agent, an anti-diabetic agent, an antihistamine, an anti-inflammatory drug, an antibiotic drug, an antimuscarinic drug, an anti-neoplastic drug, an antiviral drug, a cardiovascular drug, a central nervous system stimulator, a central nervous system depressant, an

Application No. 10/790,338

anti-depressant, an anti-epileptic, an anxyolitic agent, a hypnotic agent, a sedative, an anti-psychotic drug, a beta blocker, a hemostatic agent, a hormone, a vasodilator, a vasoconstrictor, and a vitamin.

93. (Original) The coating of claim 54 wherein the therapeutic agent comprises paclitaxel.

94. (Original) The coating of claim 54 wherein the device is selected from the group consisting of an implantable device, a device used topically on a patient, a device that contacts a living tissue, a catheter; a guide-wires, an embolizing coil; a vascular graft, a heart valve, an implantable cardiovascular defibrillator, a pacemaker, a surgical patch, a wound closure, a microsphere, a biosensors, an implantable sensor, an ex-vivo sensor, an ocular implant, a contact lens; and a tissue engineering scaffold.

95. (Original) The coating of claim 54 wherein the device comprises a stent.

96. (Original) The coating of claim 54 wherein the glass transition temperature of the first monomer unit is below about 37 degrees Centigrade and the glass transition temperature of the second monomer unit is above about 37 degrees Centigrade.

97. (Original) The coating of claim 54 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about 0 to about 60 degrees Celsius.

Application No. 10/790,338

98. (Original) The coating of claim 54 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about 15 to about 40 degrees Celsius.

99. (Original) The coating of claim 54 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about -70 to about 70 degrees Celsius.

100. (Original) The coating of claim 99 wherein the combination comprises at least one monomer unit selected from the group consisting of butyl acrylate, butyl methacrylate, and hydroxyethylmethacrylate.

101. (Original) The coating of claim 99 wherein the first monomer unit and the second monomer unit are selected from a member of the group consisting of acrylic acid, acrylonitrile, allyamine, acrylates, methacrylates, methylmethacrylate, alkyl acrylates, alkyl methacrylate, butadiene, carbomethylsilane, (carbonate) urethane, acrylates of polydimethyl siloxanes / methacrylates of polydimethyl siloxane ethylene, ethylene glycol, propylene glycol, (ether) urethane, urethane, vinyl chloride, vinyl alcohol, maleic anhydride, cellulose nitrate, carboxy methyl cellulose, dextran, dextran sulphate, propylene, esters, carbonates, ethers, butenes, maleic acid, fluoropolymer monomeric units, unsaturated polymer monomeric units, isoprene, melamine, sulphone, ureas, biological polymer monomeric units, protein, gelatin, collagen,

Application No. 10/790,338

elastin, butyl methacrylate, hydroxyethyl methacrylate, acrylic acid, methacrylate acid, polyethylene glycol dimethacrylate, polypropylene glycol diglycidal ether, polyethylene glycol diglycidyl ether, isocyanatoethyl methacrylate, N-acryloxysuccinimide, glycidyl methacrylate, hexamethylene diisocyanate, acrolein, crotonaldehyde, glycerol monomethacrylate, heparin methacrylate, methacryloyloxyethyl, methacryloylethyl phosphorylcholine polyacrylate, polyester, polyether, polyethylene glycol, butyl acrylate, polyethylene glycol monomethacrylate, isobutyl methacrylate, cyclohexyl methacrylate, ethyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, methyl acrylate, hexadecyl methacrylate, octadecyl methacrylate, styrene, methyl styrene, vinyl stearate, vinyl toluene, and tert-butyl acrylate.

102. (Original) The coating of claim 99 wherein the copolymer further comprises a third monomer unit, wherein the third monomer unit forms a homopolymer with a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of a homopolymer formed by the first monomer unit.

103. (Original) The coating of claim 99 wherein the first monomer unit comprises an acrylate, the second monomer unit comprises a methacrylate, and the third monomer unit comprises a methacrylate.

104. (Original) The coating of claim 99 wherein the copolymer comprises at least two methacrylate monomer units.

Application No. 10/790,338

105. (Withdrawn) A method of making a coating on a medical device, the method comprising associating a composition with at least a portion of the device to form a layer, wherein the composition comprises a copolymer that has a molecular weight of at least about 2500, wherein the copolymer is prepared from a room temperature melt of a plurality of monomer units that comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit.

106. (Withdrawn) The method of claim 105 wherein the melt further comprises less than about 10% by volume of a solvent.

107. (Withdrawn) The method of claim 105 wherein the melt further comprises less than about 5% by volume of a solvent.

108. (Withdrawn) The method of claim 105 wherein the melt contains essentially no solvent.

109. (Withdrawn) The method of claim 105, further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

Application No. 10/790,338

110. (Withdrawn) The method of claim 109, wherein the first layer is at least partially disposed between the device and the second layer.

111. (Withdrawn) The method of claim 109, wherein the second layer is at least partially disposed between the device and the first layer.

112. (Withdrawn) The method of claim 109, wherein the second layer comprises a polymer that is covalently crosslinked to the first layer.

113. (Withdrawn) The method of claim 109, wherein a therapeutic agent is (a) associated with the first layer but not the second layer, (b) associated with the second layer but not the first layer, or (c) both the first layer and the second layer.

114. (Withdrawn) The method of claim 113 wherein the therapeutic agent comprises paclitaxel and the device comprises a stent.

115. (Withdrawn) The method of claim 105, wherein the second monomer unit has a glass transition temperature that is at least about 50 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

Application No. 10/790,338

116. (Withdrawn) The method of claim 105, wherein the second monomer unit has a glass transition temperature that is at least about 70 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

117. (Withdrawn) The method of claim 105 wherein the first monomer unit and the second monomer unit selected from a member of the group consisting of acrylic acid, acrylonitrile, allyamine, acrylates, methacrylates, methylmethacrylate, alkyl acrylates, alkyl methacrylate, butadiene, carbomethylsilane, (carbonate) urethane, acrylates of polydimethyl siloxanes, methacrylates of polydimethyl siloxanes, ethylene, ethylene glycol, propylene glycol, (ether) urethane, urethane, vinyl chloride, vinyl alcohol, maleic anhydride, cellulose nitrate, carboxy methyl cellulose, dextran, dextran sulphate, propylene, esters, carbonates, ethers, butenes, maleic acid, fluoropolymer monomeric units, unsaturated polymer monomeric units, isoprene, melamine, sulphone, ureas, biological polymer monomeric units, protein, gelatin, collagen, elastin, butyl methacrylate, hydroxyethyl methacrylate, methacrylate acid, polyethylene glycol dimethacrylate, polypropylene glycol diglycidyl ether, polyethylene glycol diglycidyl ether, isocyanatoethyl methacrylate, N-acryloxysuccinimide, glycidyl methacrylate, hexamethylene diisocyanate, acrolein, crotonaldehyde, glycerol monomethacrylate, heparin methacrylate, methacryloyl ethyl phosphorylcholine, polymethacrylate, polyacrylate, polyester, polyether, polyethylene glycol, butyl acrylate, polyethylene glycol monomethacrylate, isobutyl methacrylate, cyclohexyl methacrylate, ethyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, methyl acrylate, hexadecyl methacrylate, octadecyl methacrylate, styrene, methyl styrene, vinyl stearate, vinyl toluene, and tert-butyl acrylate.

Application No. 10/790,338

118. (Withdrawn) The method of claim 105 wherein the copolymer further comprises a third monomer unit, wherein the third monomer unit forms a homopolymer with a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of a homopolymer formed by the first monomer unit.

119. (Withdrawn) The method of claim 105 wherein the copolymer is formed by covalently joining a homopolymer of the first monomer unit and a homopolymer of the second monomer unit.

120. (Withdrawn) The method of claim 105 wherein the associating of the composition comprises applying a therapeutic agent and the copolymer to the device approximately simultaneously to form the composition in association with the device.

121. (Withdrawn) The method of claim 105 wherein the associating of the composition comprises spraying the therapeutic agent and the copolymer on the medical device, or dipping the medical device into a mixture of the therapeutic agent and the copolymer.

122. (Withdrawn) The method of claim 105 wherein the monomer units are polymerized to form the copolymer after the monomer units have been associated with the medical device.

Application No. 10/790,338

123. (Withdrawn) The method of claim 122 wherein the medical device is heated to polymerize the monomer units to form the copolymer.

124. (Withdrawn) The method of claim 122 wherein an initiator is associated with the monomer units and the initiator is activated to cause the polymerization of the monomer units to form the copolymer.

125. (Withdrawn) The method of claim 122 wherein the medical device is a stent and the therapeutic agent is paclitaxel.

126. (Withdrawn) The method of claim 125 further comprising implantating the device into a patient resulting in the release of the paclitaxel from the stent.

127. (Withdrawn) The method of claim 105 wherein the copolymer is prepared and is subsequently associated with the therapeutic agent.

128. (Withdrawn) The method of claim 105 wherein the copolymer is prepared from the monomer units from a melt of the monomers.

129. (Withdrawn) The method of claim 105 wherein the first monomer unit and the second monomer unit are chosen so that the first monomer unit reacts to form a plurality of blocks

Application No. 10/790,338

consisting essentially of repeats of the first monomer unit and the second monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the second monomer unit.

130. (Withdrawn) The method of claim 300 further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

131. (Withdrawn) The method of claim 130 wherein the first layer is at least partially disposed between the device and the second layer.

132. (Withdrawn) The method of claim 130 wherein the second layer is at least partially disposed between the device and the first layer.

133. (Withdrawn) The method of claim 130 wherein the second layer comprises a polymer that is covalently crosslinked to the polymer of the first layer.

134. (Withdrawn) The method of claim 130 wherein the copolymer comprises reactive functional groups that are involved in forming covalent crosslinks with the second layer, and wherein the reactive functional groups are chosen from the group consisting of hydroxyl, amine, carboxylic, aldehyde, ketone, thiol, allyl, acrylate, methacrylate, isocyanate, epoxide, azides, aziridines, acetals, ketals, alkynes, acyl halides, alkyl halides, hydroxy aldehydes and ketones, allenes, amides, bisamides, amino acids and esters, amino carbonyl compounds, mercaptans,

Application No. 10/790,338

amino mercaptans, anhydrides, azines, azo compounds, azoxy compounds, boranes, carbamates, carbodimides, carbonates, diazo compounds, isothionates, hydroxamic acid, hydroxy acids, hydroxy amines and amides, hydroxylamine, imines, lactams, nitriles, sulphonamides, sulphones, sulphonic acids, thiocyanates, and combinations thereof.

135. (Withdrawn) The method of claim 130 wherein the second layer comprises a heparin macromer that comprises a second reactive functional group that is involved in forming the crosslinks with the first layer.

136. (Withdrawn) The method of claim 130 wherein the polymer of the second layer comprises a second functional group that forms at least one of the covalent crosslinks in response to exposure to light.

137. (Withdrawn) The method of claim 130 wherein the first layer comprises the therapeutic agent and the second layer does not comprise the therapeutic agent.

138. (Withdrawn) The method of claim 130 wherein the second layer reduces the rate of release of the therapeutic agent from the first layer.

139. (Withdrawn) The method of claim 130 wherein the second layer is in contact with the medical device and comprises a polymer having at least one reactable monomer.

Application No. 10/790,338

140. (Withdrawn) The method of claim 130 wherein the polymer in the second layer is a second copolymer that comprises monomer units of at least one member of the group consisting of vinyl chloride, vinyl acetate, and co-vinyl alcohol.

141. (Withdrawn) The method of claim 105 wherein the therapeutic agent is a member of the group consisting of vasoactive agents, neuroactive agents, hormones, growth factors, cytokines, anaesthetics, steroids, anticoagulants, anti-inflammatories, immunomodulating agents, cytotoxic agents, antibiotics, antivirals, antibodies, anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, antibodies capable of blocking smooth muscle cell proliferation, hirudin, acetylsalicylic acid; anti-inflammatory agents, dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; anticoagulants, D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, antiplatelet peptides, vascular cell growth promoters, growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, translational promoters, vascular cell growth inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, cholesterol-lowering agents, vasodilating agents, agents which interfere with endogenous vasoactive mechanisms, a

Application No. 10/790,338

radiopharmaceutical, an analgesic drug, an anesthetic agent, an anorectic agent, an anti-anemia agent, an anti-asthma agent, an anti-diabetic agent, an antihistamine, an anti-inflammatory drug, an antibiotic drug, an antimuscarinic drug, an anti-neoplastic drug, an antiviral drug, a cardiovascular drug, a central nervous system stimulator, a central nervous system depressant, an anti-depressant, an anti-epileptic, an anxiolytic agent, a hypnotic agent, a sedative, an anti-psychotic drug, a beta blocker, a hemostatic agent, a hormone, a vasodilator, a vasoconstrictor, and a vitamin.

142. (Withdrawn) The method of claim 105 wherein the therapeutic agent comprises paclitaxel.

143. (Withdrawn) The method of claim 105 wherein the device is selected from the group consisting of an implantable device, a device used topically on a patient, a device that contacts a living tissue, a catheter; a guide-wires, an embolizing coil; a vascular graft, a heart valve, an implantable cardiovascular defibrillator, a pacemaker, a surgical patch, a wound closure, a microsphere, a biosensors, an implantable sensor, an ex-vivo sensor, an ocular implant, a contact lens; and a tissue engineering scaffold.

144. (Withdrawn) The method of claim 105 wherein the device comprises a stent.

145. (Withdrawn) The method of claim 105 wherein the therapeutic agent comprises paclitaxel and the device comprises a stent.

Application No. 10/790,338

146. (Withdrawn) The method of claim 105 wherein the glass transition temperature of the first monomer unit is below about 37 degrees Centigrade and the glass transition temperature of the second monomer unit is above about 37 degrees Centigrade.

147. (Withdrawn) The method of claim 105 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about -70 to about 70 degrees Celsius.

148. (Withdrawn) The method of claim 105 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about 0 to about 60 degrees Celsius.

149. (Withdrawn) The method of claim 105 wherein the copolymer is made from a combination of monomer units, wherein the combination has a weight-averaged average monomer unit glass transition temperature in a range of about 15 to about 40 degrees Celsius.

150. (Withdrawn) The method of claim 149 wherein the therapeutic agent and the copolymer are applied to the device approximately simultaneously.

151. (Original) An expandable medical device associated with a material for delivery of a therapeutic agent, the material comprising a composition associated with at least a portion of an expandable portion of the expandable medical device, wherein the composition comprises the

Application No. 10/790,338

therapeutic agent associated with a copolymer that has a molecular weight of at least about 2500, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit with at least a portion of an expandable portion of a medical device.

152. (Original) The coating of claim 151 wherein at least a portion of the first monomer units are organized into a plurality of blocks consisting essentially of repeats of the first monomer unit, and at least a portion of the second monomer units are organized into a plurality of blocks consisting essentially of repeats of the second monomer unit.

153. (Original) The coating of claim 152 wherein the copolymer further comprises regions of random copolymer bonding.

154. (Original) The coating of claim 152 wherein the copolymer comprises acrylate blocks and methacrylate blocks.